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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALTANA PHARMA AG, and WYETH Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	Civil Action No.: 04-2355 (JLL)

TEVA PHARMACEUTICALS USA, INC.'S ANSWER AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc. (hereinafter "Teva USA"), by its attorneys, for its Answer responds as follows:

THE PARTIES

1. Teva USA is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶1 of the Complaint and, therefore, denies them.

2. Teva USA is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 2 of the Complaint and, therefore, denies them.

3. Paragraph 3 is not a factual or legal allegation and requires no response.

4. Teva USA admits that it is a corporation incorporated under the laws of the State of Delaware and that its principal place of business and corporate offices are in Pennsylvania. Teva USA admits that it has offices at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090, and has places of businesses at 1801 River Road, Fairlawn, NJ 07410 and 8-10 Gloria Lane, Fairfield, NJ 07004. To the extent not admitted, Teva USA denies the remaining allegations found in ¶ 4.

5. Paragraph 5 is not directed to Teva USA, and requires no response. Teva USA cannot speak for Teva Pharmaceutical Industries, Ltd. ("Teva Israel"). Therefore, to the extent that any of the allegations in the Complaint pertain to Teva Israel, Teva USA denies them.

6. Teva USA admits that it is a subsidiary of Teva Israel and that there is some overlap in the directors and/or officers of the two companies.

7. Teva USA denies the allegations in ¶ 7 of the Complaint.

8. Paragraph 8 is not a factual or legal allegation and requires no response.

9. Admitted.

10. Teva USA admits that it sells pharmaceuticals throughout the United States, including in New Jersey, including materials it obtains from Teva Israel. Teva USA denies the

remaining allegations found in ¶ 10 of the Complaint, including all allegations directed to Teva Israel.

11. Teva USA admits that this purports to be a civil action arising under the patent laws of the United States of America and that for the purposes of this litigation only, jurisdiction and venue are proper in this Court as to Teva USA only. To the extent not admitted, Teva USA is without information sufficient for relief as to the truth or falsity of the remaining allegations found in ¶ 11 and, therefore, denies them.

12. Upon information and belief, Teva USA admits that New Drug Application No. 20-987 was approved by the United States Food & Drug Administration for 20 mg and 40 mg delayed-release tablets including the active ingredient pantoprazole sodium. Upon information and belief, Teva USA admits that tablets including pantoprazole are promoted in the United States under the trade name "PROTONIX®". To the extent not admitted, Teva USA is without information sufficient for relief as to the truth or falsity of the remaining allegations found in ¶ 12 and, therefore, denies them.

13. Teva USA admits claim 1 of the '579 patent claims a dialkoxypyridine. The remaining claims speak for themselves. Teva USA is without information sufficient to form a belief as to the truth or falsity of the remaining allegations found in ¶ 13 of the Complaint and, therefore, denies them.

14. Teva USA is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 14 of the Complaint and, therefore, denies them.

15. Teva USA admits that a copy of the '579 patent was attached as Exhibit A to the Complaint.

16. Teva USA admits that Teva USA filed an Abbreviated New Drug Application ("ANDA"), including a certification with respect to the '579 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) seeking approval to sell pantoprazole sodium tablets. Teva USA denies the remaining allegations found in ¶ 16 of the Complaint, including all allegations directed to Teva Israel.

17. Teva USA admits that in the event Teva USA's ANDA for pantoprazole sodium is approved, Teva Israel is the presently intended manufacturer for finished dosage products in ANDA No. 77-056. Teva USA denies the remaining allegations found in ¶ 17 of the Complaint, including all allegations directed to Teva Israel.

18. Teva USA admits that on or about April 6, 2004, Teva USA sent a notice to Altana and Wyeth Pharmaceuticals in which Teva USA represented that Teva USA had filed an ANDA for pantoprazole sodium delayed-release tablets in the United States. Teva USA further admits that in its April 6, 2004, notice, it included a certification with respect to the '579 patent, and stated that it seeks approval of ANDA No. 77-056 prior to the expiration of the '579 patent. Teva USA denies the remaining allegations found in ¶ 18 of the Complaint, including all allegations directed to Teva Israel.

19. Teva USA is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 19 of the Complaint and, therefore, denies the same.

20. Teva USA is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 20 of the Complaint and, therefore, denies the same.

21. Teva USA admits that Teva USA seeks approval of ANDA No. 77-056 prior to the expiration of the '579 patent. Teva USA admits that the filing of its ANDA is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) which creates jurisdiction for the district court to

determine that Teva USA's proposed Pantoprazole sodium delayed-release tablets, 20 mg and 40 mg base, do not infringe any valid and enforceable claim of the '579 patent. Teva USA denies the remaining allegations found in ¶ 21 of the Complaint, including all allegations directed to Teva Israel.

22. Teva USA denies the allegations in ¶ 22 of the Complaint.

23. Teva USA admits that it was aware of the existence of the '579 patent before it filed its ANDA. Teva USA admits that the filing of its ANDA is a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) which is necessary to create jurisdiction under section 505(j) of the Hatch Waxman Act for the district court to determine that Teva USA's proposed Pantoprazole sodium delayed-release tablets, eq. 20 mg and 40 mg base, do not infringe any valid and enforceable claim of the '579 patent. Teva USA denies the remaining allegations found in ¶ 23 of the Complaint, including all allegations directed to Teva Israel.

24. Teva USA denies the allegations in ¶ 24 of the Complaint.

25. Teva USA denies the allegations in ¶ 25 of the Complaint.

26. Teva USA denies the allegations in ¶ 26 of the Complaint.

PRAYER FOR RELIEF

27. In response to Plaintiffs' prayer for relief in the Complaint:

A. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(a) of the Prayer for Relief.

B. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(b) of the Prayer for Relief.

C. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(c) of the Prayer for Relief.

D. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(d) of the Prayer for Relief.

E. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(e) of the Prayer for Relief.

F. Teva USA denies that Plaintiffs are entitled to the relief requested in ¶ 27(f) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

28. Teva USA will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

SECOND AFFIRMATIVE DEFENSE

29. Upon information and belief, the claims of the '579 patent are invalid under 35 U.S.C. § 103.

COUNTERCLAIMS

Teva USA, for its counterclaims against Plaintiff, alleges as follows:

THE PARTIES

1. Teva USA is a corporation incorporated under the laws of the State of Delaware. Teva USA has offices at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

2. Upon information and belief, Altana is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

3. Upon information and belief, Wyeth is a Delaware corporation with its headquarters located at Five Giralda Farms, Madison, New Jersey 07940.

JURISDICTION

4. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. The counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Food and Drug Laws of the United States, 21 U.S.C. § 355. Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. Altana Pharma AG (hereinafter "Altana") and Wyeth have filed a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. (hereinafter "Teva USA") and Teva Pharmaceutical Industries, Ltd., in the District of New Jersey.

FACTUAL BACKGROUND

6. Upon information and belief, Altana is currently the owner of the '579 patent.

7. Upon information and belief, Wyeth Pharmaceuticals, Inc., a wholly owned subsidiary of Wyeth, holds an improved New Drug Application from the FDA for pantoprazole sodium delayed-release tablets.

8. Teva USA has filed ANDA No. 77-056 for approval to market a pantoprazole sodium delayed-release tablet, eq. 20 mg and 40 mg base in the United States.

9. Teva USA sent a notice letter related to ANDA No. 77-056 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to Wyeth and Altana on April 6, 2004, which notice letter, upon

information and belief, was received by Altana on or about April 8, 2004, and Wyeth on or about April 7, 2004.

10. On or about May 20, 2004, Altana and Wyeth filed or caused to be filed a Complaint for patent infringement that alleges that Teva USA infringes the '579 patent.

COUNT I

INVALIDITY OF THE '579 PATENT

11. The allegations of ¶¶ 1 - 10 are repeated, realleged, and incorporated herein by reference.

12. Upon information and belief, the claims of the '579 patent are invalid under 35 U.S.C. § 103.

COUNT II

NON-INFRINGEMENT OF THE '579 PATENT

13. The allegations of ¶¶ 1 - 12 are repeated, realleged and incorporated herein by reference.

14. Teva USA will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Teva USA prays that the Court enter:

A. A declaratory judgment that Teva USA will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271;

B. A declaratory judgment that the '579 patent is invalid;

C. An Order enjoining and restraining Altana and Wyeth and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them

from further charges of infringement or acts of enforcement based on the '579 patent against Teva USA or its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Teva USA; and

D. An Order awarding Teva USA such other further relief as the Court deems just and equitable.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: June 18, 2004

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